Exhibit M

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Silver Spring, MD 20993

March 1, 2010

Arthur P. Bedrosian, J.D., President
Lannett Company, Inc.
9000 State Road
Philadelphia, PA 19136

Product: Morphine Sulfate Solution Immediate Release 20 mg/ml

Dear Mr. Bedrosian:

This letter is written in reference to the March 30, 2009 warning letter (Warning Letter) your firm received for distributing morphine sulfate oral solution 20 mg/ml, an unapproved new drug, in violation of the Federal Food, Drug, and Cosmetic Act (the Act). This letter is also in reference to the April 9, 2009 follow-up letter your firm received extending the period during which the Food and Drug Administration (FDA) would exercise enforcement discretion with regard to the product listed above to 180 days after any firm receives approval for morphine sulfate oral solution 20 mg/ml.

On January 25, 2010, FDA approved Roxane Laboratories supplemental new drug application (NDA) for its Morphine Sulfate Oral Solution 100 mg/5mL (20 mg/mL). Therefore, in accordance with the terms of the April 9, 2009, letter, we will exercise enforcement discretion with regard to the shipment/distribution of the product listed above until July 24, 2010. If your firm ships/distributes your unapproved morphine sulfate oral solution 20 mg/ml product beyond July 24, 2010, that activity may result in legal action without further notice, including, without limitation, seizure and injunction.

We encourage you to adjust manufacturing to prevent surplus morphine sulfate oral solution 20 mg/ml that may need to be destroyed. A copy of this letter will be forwarded to DEA.

The mission of FDA's Center for Drug Evaluation and Research (CDER) is to assure that safe and effective drugs are available to the American people. The drug approval system is one of the essential means by which CDER achieves its mission and ensures that patients have access to drugs of proven safety, efficacy, and quality. FDA has worked to ensure that patient needs will continue to be met and has been in communication with Roxane Laboratories, the manufacturer of the approved Morphine Sulfate Oral Solution 20 mg/ml product, about the supply of its approved product. Roxane Laboratories has informed FDA that it anticipates it will be able to continue to meet patient needs and therefore no shortages are expected.

FDA continues its commitment to take enforcement action against the marketing of unapproved drugs, in an effort to ensure that drugs used by patients are safe and effective. We remind you

that all firms that market unapproved drugs to the American public are expected to submit the required applications to obtain approval for those products. It is your responsibility to assure that your firm complies with all requirements of federal law and FDA regulations. We encourage firms marketing any unapproved drugs to obtain FDA's approval for their products. For assistance please contact the unapproved drugs coordinator in the Office of New Drugs at 301-796-0700, or the Office of Generic Drugs at 240-276-9310.

If you have any questions regarding this letter, please contact Ms. Sakineh Walther, Compliance Officer, at the U.S. Food and Drug Administration, Center for Drug Evaluation and Research, Office of Compliance, WO51 RM 5242, 10903 New Hampshire Avenue, Silver Spring, MD 20993.

Sincerely yours,

/Deborah M. Autor/
Deborah M. Autor, Esq.
Director
Office of Compliance
Center for Drug Evaluation and Research
Food and Drug Administration

Exhibit N

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Silver Spring, MD 20993

March 1, 2010

Richard E. Asherman, CEO
Cody Laboratories, Inc.
601 Yellowstone Avenue
Cody, Wyoming 82414

Product: Morphine Sulfate Solution Immediate Release 20mg/ml

Dear Mr. Asherman:

This letter is written in reference to the March 30, 2009 warning letter (Warning Letter) your firm received for manufacturing and distributing morphine sulfate oral solution 20 mg/ml, an unapproved new drug, in violation of the Federal Food, Drug, and Cosmetic Act (the Act). This letter is also in reference to the April 9, 2009 follow-up letter your firm received extending the period during which the Food and Drug Administration (FDA) would exercise enforcement discretion with regard to the product listed above to 180 days after any firm receives approval for morphine sulfate oral solution 20 mg/ml.

On January 25, 2010, FDA approved Roxane Laboratories supplemental new drug application (NDA) for its Morphine Sulfate Oral Solution 100 mg /5 ml (20 mg/ml). Therefore, in accordance with the terms of the April 9, 2009, letter, we will exercise enforcement discretion with regard to the manufacturing and shipment/distribution of the product listed above until July 24, 2010. If your firm manufacturers or ships/distributes your unapproved morphine sulfate oral solution 20 mg/ml product beyond July 24, 2010, that activity may result in legal action without further notice, including, without limitation, seizure and injunction.

We encourage you to adjust manufacturing to prevent surplus morphine sulfate oral solution 20 mg/ml that may need to be destroyed. A copy of this letter will be forwarded to DEA.

The mission of FDA's Center for Drug Evaluation and Research (CDER) is to assure that safe and effective drugs are available to the American people. The drug approval system is one of the essential means by which CDER achieves its mission and ensures that patients have access to drugs of proven safety, efficacy, and quality. FDA has worked to ensure that patient needs will continue to be met and has been in communication with Roxane Laboratories, the manufacturer of the approved Morphine Sulfate Oral Solution 20 mg/ml product, about the supply of its approved product. Roxane Laboratories has informed FDA that it anticipates it will be able to continue to meet patient needs and therefore no shortages are expected.

FDA continues its commitment to take enforcement action against the marketing of unapproved drugs, in an effort to ensure that drugs used by patients are safe and effective. We remind you that all firms that market unapproved drugs to the American public are expected to submit the required applications to obtain approval for those products. It is your responsibility to assure that your firm complies with all requirements of federal law and FDA regulations. We encourage firms marketing any unapproved drugs to obtain FDA's approval for their products. For assistance please contact the unapproved drugs coordinator in the Office of New Drugs at 301-796-0700, or the Office of Generic Drugs at 240-276-9310.

If you have any questions regarding this letter, please contact Ms. Sakineh Walther, Compliance Officer, at the U.S. Food and Drug Administration, Center for Drug Evaluation and Research, Office of Compliance, WO51 RM 5242, 10903 New Hampshire Avenue, Silver Spring, MD 20993.

Sincerely yours,

/Deborah M. Autor/
Deborah M. Autor, Esq.
Director
Office of Compliance
Center for Drug Evaluation and Research
Food and Drug Administration

Exhibit O

Lannett

Lannett Company, Inc.
9000 State Road, Philadelphia, PA 19136
Telephone: 215-333-9000 • Fax: 215-333-9004
www.lannett.com

March 4, 2010

VIA E-MAIL (deborah.autor@fda.hhs.gov)
(Original Sent By Regular Mail)

Deborah M. Autor, Esq.
Director
Office of Compliance
Center for Drug Evaluation and Research
Food and Drug Administration
10903 New Hampshire Avenue
White Oak, Building 51, Office #5270
Silver Spring, MD 20993-0002

Re: Morphine Sulfate Solution Immediate Release 20 mg/mL

Dear Ms. Autor:

Our affiliate Cody Laboratories and the Lannett Company are in receipt of letters dated March 1, 2010 informing us of the January 25, 2010 FDA approval of a supplemental new drug application (NDA) for a morphine sulfate oral solution 100 mg/5 mL (20 mg/mL) by Roxane Laboratories. You state that if we ship/distribute our "unapproved [MS] product beyond July 24, 2010, that activity may result in legal action without further notice, including, without limitation, seizure and injunction." You further encourage us "to adjust manufacturing to prevent surplus [MS] that may need to be destroyed," stating that "a copy of this letter will be forwarded to the DEA." Finally you state that "Roxane Laboratories has informed FDA that it anticipates it will be able to continue to meet patient needs and therefore no shortages are expected." The letter follows the submission by Lannett on February 26, 2010 of its own NDA seeking approval of MS.

Your letter will likely become public and will be used by Roxane to continue to expand its market share of this drug. It also follows the issuance of a press release, teleconference, republication of the original March 30, 2009 warning letter (but not the April 9, 2009 extension), and communications with Lannett's major customers (and their trade associations), as well as the Drug Enforcement Administration (DEA) opposing further quota for Lannett, highlighting that the Roxane drug is now available pursuant to its approved NDA.

We can only hope that Lannett will receive the same interaction and cooperation with the agency that Roxane received to bring its competing 20 mg/mL formulation to market (at the agency's request). It appears that the Roxane supplemental NDA was submitted and approved within 5 months (submitted August 25, 2009 and approved January 26, 2010). There is also 5 months available between Lannett's submission date and the date FDA proposes to use its enforcement discretion in this matter. Please continue to help us work cooperatively with you, and Sharon Hertz in the review division, to prioritize review of that application in recognition that, like Roxane, Lannett has helped alleviate product shortage and responsibly seek regulatory approval of its MS product through preparation and submission of an NDA.

Thank you for your consideration of this matter, and for your continued assistance.

Sincerely,

Arthur P. Bedrosian

cc: Douglas Throckmorton, M.D. (via email)
Michael Levy, Esq. (via email)
Ms. Alisea Crowley (via email)
Sharon Hertz, M.D. (via email)
Ms. Amy Muhlburg (via email)

Exhibit P

Scheineson, Marc

From:	Scheineson, Marc
Sent:	Thursday, June 10, 2010 12:18 PM
To:	'sharon.hertz@fda.hhs.gov'; Levy, Michael
Cc:	'janet.woodcock@fda.hhs.gov'; 'douglas.throckmorton@fda.hhs.gov'; Autor, Deborah; 'bob.rappaport@fda.hhs.gov'; 'donna.katz@fda.hhs.gov'; 'Muhlberg, Amy (HELP Committee)'; Campbell, Regina (Specter); 'Arthur Bedrosian'; Ernest Sabo; Segal, Donald
Subject:	FW: Lannett Company- Morphine Sulfate
Importance:	High

We appreciate your continued dialogue, and cooperation, regarding the approval of morphine sulfate made by the Lannett Company and Cody Labs. As you know, Lannett has marketed this drug safely for 4 years, and supplies a majority of the US market for this particular formulation.

Another "crisis point" (for the Company) is nearing that we highlight for your review and consideration. This is a unique situation. FDA seeks to exercise its enforcement discretion under its Unapproved Drugs Guidance to remove a drug from the market despite **full sponsor cooperation and no expressed safety concern**. Below are the relevant facts (as we understand them), upon which we request your cooperation and advice. Thank you for your consideration and response.

* On March 1, 2010, FDA-CDER Compliance issued a warning letter to Lannett (modified on April 9, 2009) stating that Lannett's morphine sulfate concentrated solution (20mg/mL) ("MS") must be withdrawn from the market **by July 24, 2010** (180-days following approval of a first NDA).

* Lannett cooperated fully with FDA to alleviate a drug shortage caused by the warning letter. (This concentrated morphine formulation is used for hospice care of terminally ill patients who cannot swallow much liquid or accept the drug intravenously.)

* Lannett submitted a NDA (505(b)(2)), at the Agency's request, in late January 2010. This data was prepared despite an opinion from experienced regulatory counsel (me) that the MS product is "grandfathered" under the '38 Act, so prior marketing approval is not required legally.

* Lannett received word that its NDA application will not be expedited. In fact, the review has reportedly slowed down over issues such as the request for a Risk Evaluation and Remediation Strategy plan (REMS) (which we hope can be satisfied through the use of a MedGuide similar to what was required for Roxane).

* FDA worked interactively with Roxane in a very unusual manner to persuade the company to make the 20mg/mL formulation, and expedited the NDA review/approval to 5 months (the same time period that Lannett seeks).

* Based on FDA's announced compliance position, the Drug Enforcement Administration (DEA) is prepared to deny Lannett additional product quota, and the Center for Medicare and Medicaid Services (CMS) is prepared to deny reimbursement.

* **We respectfully request that FDA either: (1) "maintain a level playing field" by expediting review of Lannett's NDA using the same data and standards applied to Roxane; or (2) exercise its enforcement discretion to maintain Lannett's MS on the market since the Company has cooperatively sought product approval which is the stated objective of the Guidance.**

Thank you for your cooperation and advice in this matter. My colleagues and I would be happy to meet, or to provide any additional information that you might require. Best, Marc.

Marc J. Scheineson, Esq.
Alston & Bird LLP
The Atlantic Building
950 F Street NW
Washington, D.C. 20004
202-756-3465 (O)
202-756-3333(FAX)
marc.scheineson@alston.com

Exhibit Q

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Silver Spring, MD 20993-0002

June 22, 2010

Marc J. Scheineson, Esq.
Alston & Bird LLP
The Atlantic Building
950 F Street NW
Washington, D.C. 20004

Dear Mr. Scheineson:

This letter responds to your June 10, 2010, email correspondence requesting that the Food and Drug Administration (FDA) either: "(1) "maintain a level playing field" by expediting review of Lannett's NDA using the same data and standards applied to Roxane; or (2) exercise its enforcement discretion to maintain Lannett's MS on the market since the Company has cooperatively sought product approval which is the stated objective of the Guidance."

Please refer to my response letter to Mr. Arthur Bedrosian regarding this same issue (copy attached). In addition, Lannett's initial request in March 2010 for expedited review to the Center for Drug Evaluation and Research (CDER), Division of Anesthesia and Analgesia Products (DAAP), was denied because at the time of the request:

1. There was no drug shortage for Morphine Sulfate Oral Solution, 20 mg/ml;
2. There was an approved product on the market;
3. The information from the CDER Drug Shortage staff confirmed that the approved product could cover the market.

The initial Roxane NDA (022195) for 5 mg/5mL and 20 mg/5mL received a priority review as did the supplement for the 100 mg/5mL (20 mg/mL) because they were all medically necessary. There was a drug shortage when the Morphine Sulfate Oral Solution, 20 mg/ml application was filed and DAAP worked to get that approved as early as they could so the shortage could be addressed.

Regarding your statement that the "review has reportedly slowed down over issues such as the request for a Risk Evaluation and Mitigation Strategies plan (REMS)," a medication guide REMS for this product is required because of medication errors associated with the oral solutions. This remains consistent with the application process for other similar products, including Roxane's NDA 022195. It is my understanding this is not expected to create a delay as DAAP notified Lannett early and communicated the specific requirements.

Regarding your statement that Lannett submitted an NDA (505(b)(2)) in January 2010,[1] "despite an opinion from experienced regulatory counsel (me) that the MS product is "grandfathered" under the '38 Act, so prior marketing approval is not required legally," we have thoroughly discussed – and put to rest -- this matter in previous correspondence. Following the issuance of the March 31, 2009 Warning Letter to Lannett and Cody, you protested the FDA's action. We worked with you to address your concerns in two face to face meetings, reviewed and found inadequate two large volume submissions for your "grandfather claim," and replied to numerous emails addressed to me. As stated in FDA's November 2009 response letter regarding your "grandfather" claim, we disagree with your interpretation of the 1938 "grandfather" clause and are not persuaded by your arguments. Based on our review of the information you have provided, and consistent with FDA's longstanding interpretation of the 1938 grandfather clause, Lannett and Cody's Morphine Sulfate Oral Solution, 20 mg/ml, is an unapproved new drug for which there is no FDA-approved application on file, and it is not grandfathered.

While we are encouraged that you are seeking approval for your product, Roxane's FDA-approved Morphine Sulfate Oral Solution, 20 mg/ml, can meet patient supply needs. I reiterate FDA's intention to take action against firms that do not conform to the terms set forth in the March 31, 2009 Warning Letters, and FDA's follow up letter on April 1, 2010, by continuing distribution of unapproved Morphine Sulfate Oral Solution, 20 mg/ml, after July 24, 2010.

Sincerely,

Deborah M. Autor, Esq.
Director
Office of Compliance
Center for Drug Evaluation and Research

Cc: Denver district office
New Jersey district office

Attachment: Response to March 2010 letter from Mr. Bedrosian

[1] Actual date of submission received is March 1, 2010 per DARRTS

MAR 13 2010

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Silver Spring, MD 20993-0002

Mr. Arthur Bedrosian
Lannett Company, Inc.
9000 State Road
Philadelphia, PA 19136

Dear Mr. Bedrosian:

This letter responds to your letter dated March 4, 2010, concerning your unapproved morphine sulfate solution immediate-release (20 mg/ml). In your letter, you have expressed the desire to receive the same interaction and cooperation with the Agency that Roxane Laboratories, Inc. received to bring its competing morphine sulfate solution 20mg/ml formulation to market.

FDA will do what it can to encourage the timely development of an approved formulation of this drug by your company. However, FDA's review cycle and approval of a new drug application depends on several factors including the quality of data submitted in the application, whether it is the first approval of a medically necessary or life saving drug, current market availability, and pre-approval inspection results. Therefore, there is no guarantee that you will get an expedited review.

I would like to reiterate FDA's intention to take action against firms that do not conform to the requirements set forth in the March 1, 2010 letter by continuing distribution of unapproved morphine sulfate solution immediate-release (20 mg/ml) after July 24, 2010.

Sincerely,

Deborah M. Autor, Esq.
Director
Office of Compliance
Center for Drug Evaluation and Research

Exhibit R – See Exhibit K to Memorandum of Law in Support of Plaintiffs' Motion for Temporary Restraining Order and Preliminary Injunction

From: McMeekin, Judith [mailto:Judith.McMeekin@fda.hhs.gov]
Sent: Tuesday, July 20, 2010 5:01 PM
To: greg.yonko@mckession.com; neil.warren@cardinal.com; Mays, Steve
Cc: Levy, Michael; Walther, Sakineh H; Jensen, Valerie E; Anderson, Kathleen R
Subject: Distribution of unapproved concentrated morphine sulfate solution

Dear Sir,

On March 1, 2010, firms distributing unapproved morphine sulfate oral solution 20 mg/ml were notified that the Food and Drug Administration (FDA) would exercise enforcement discretion until 180 days after any firm receives approval for morphine sulfate oral solution 20 mg/ml.

On January 25, 2010, FDA approved Roxane Laboratories' supplemental new drug application (NDA) for its morphine sulfate oral solution 100 mg/5mL (20 mg/mL). Therefore, FDA will exercise enforcement discretion with regard to the shipment/distribution of the product listed above only until July 24, 2010. Any firm (including wholesalers) distributing unapproved morphine sulfate oral solution 20 mg/ml after July 24, 2010, is at risk of regulatory action.

FDA is committed to making sure that patients have access to drugs of proven safety, efficacy, and quality and hopes that your firm shares this same commitment. If you have any additional questions concerning this letter, please contact Ms. Sakineh Walther, Compliance Safety Officer, at the U.S. Food and Drug Administration, Center for Drug Evaluation and Research, Office of Compliance, WO51 RM 5242, 10903 New Hampshire Avenue, Silver Spring, MD 20993.

Thanks.
Mike
Michael Levy
Director, Division of New Drugs and Labeling Compliance
Office of Compliance
Center for Drug Evaluation and Research
FDA